

53. Diagnostic kit for the detection of group O HIV-1 specific antibodies comprising at least one synthetic peptide of formula (I) according to claim 44 and appropriate means of detection of complexes between said antibodies and said peptides.

Final
54. Diagnostic kit for the detection of group O HIV-1 specific antibodies comprising a composition according to claim 47 and appropriate means of detection of complexes between said antibodies and peptides from said composition.

REMARKS

New claims 44-54 are submitted, hereby, in place of claims 31-43.

Claim 44 combines subject matter from claims 31, 33 and 34. Claims 45-54 correspond to claims 32 and 35-43, respectively, revised to depend on claim 44. Claims 41-54 represent changes to claims 40-43 as explained below.

Reconsideration is requested in connection with the rejection under 35 USC 112, ¶1.

The statement of rejection contends that the scope of the claims would be too broad in view of the compounds shown in examples. Applicants do not agree. It is well established that working examples are not necessary when one possessed of knowledge of ordinary skill in the art could practice the invention without the exercise of undue experimentation. *Ex parte Nardi*, 229 USPQ 79 (BPA & I 1986). Lack of enablement under §112 is not established by mere allegations of undue breadth, that is, by merely arguing that claims read on non-disclosed embodiments. *Horton v.*

Stevens, 7 USPQ2d 1245 (BPA & I 1988). Lack of enablement under §112 is not established by mere allegations of undue breadth, that is, by merely arguing that claims read on non-disclosed embodiments. *Horton v. Stevens*, 7 USPQ2d 1245 (BPA & I 1988). However, to move prosecution of the application forward, claim 31 is amended as claim 43 so as to define group Z as shown in claim 34, and group Ω as shown in claim 33.

Accordingly, claims 33 and 34 are canceled and claim dependency is revised. The rejection under 35 USC § 112, first paragraph, is deemed moot in view of the instant amendment.

Reconsideration is requested, in view of the instant amendment, of the rejection under 35 USC 112, second paragraph.

According to the statement of rejection, claims 40 and 41, that relate to an immunoassay method, are unclear for reciting that the used peptide is "previously detectably labeled," and the claimed method allegedly fails to point out the steps to be carried out.

The instant Amendment deletes the term "previously" and rewords claims 40 and 41 as shown in claims 51 and 52 submitted herewith.

Claims 42 and 43 are drawn to a diagnostic kit comprising a peptide or a composition according to the instant invention. According to the statement of rejection, the claims should further set forth the characteristics of the kit, e.g., containers, reagents, etc. Accordingly, replacement claims 53 and 54 read:

53. A diagnostic kit for the detection of HIV-1 group O specific antibodies comprising a synthetic peptide for formula (I) according to claim 31 and appropriate means of detection of complexes between said antibodies and said peptides.
54. A diagnostic kit for the detection of HIV-1 group O specific antibodies comprising a composition according to claim 36 and appropriate means of detection of complexes between antibodies and peptides from said composition."

The specification provides at least inherent support for the amendment represented by claims 53 and 54. To comply with the written description requirement the specification need not describe the claimed invention *in ipso verbis*." *In re Edwards*, 196 USPQ 465 (CCPA 1978). The proper test is whether the disclosure reasonably conveys to the skilled artisan that the inventor had possession of the claimed subject matter. *Id.* The only essential component of the kit is the peptide or composition of the instant invention. Furthermore, versatility of the immunoassays likely to be performed using the claimed kit is such that it would be unduly limiting to list of all elements that the kit could contain. One skilled in the art would readily know what are the appropriate means, depending on the format of the assay for which the kit is to be used.

Request for Initialed Forms PTO 1449

In the Office Action mailed March 29, 2001, the Examiner acknowledged consideration of the references cited in the Information Disclosure Statement filed December 8, 1998 and October

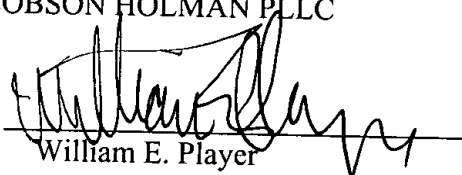
2, 2000. Applicants request that the Examiner return the Forms PTO 1449, initialed by the Examiner.

Favorable action is requested..

Respectfully submitted,

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